

Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this subchapter and related matters assigned by the Commissioner.

(f) Office to assist small tobacco product manufacturers

The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this chapter.

(g) Consultation prior to rulemaking

Prior to promulgating rules under this subchapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

(June 25, 1938, ch. 675, §901, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1786.)

Editorial Notes

REFERENCES IN TEXT

The Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (c)(1), is div. A of Pub. L. 111-31, June 22, 2009, 123 Stat. 1776. Section 101(a) of title I of the Act amended section 321 of this title. Section 102 of title I of the Act enacted section 387a-1 of this title. Section 103 of title I of the Act amended sections 331, 333, 334, 355, 360m, 372 to 374, 375, 379a, 381, 393, 399, and 679 of this title and enacted provisions set out as notes under sections 331, 333, and 387c of this title. Title II of the Act amended sections 1333, 1334, 4402, and 4406 of Title 15, Commerce and Trade, and enacted provisions set out as notes under sections 1333 and 4402 of Title 15. Title III of the Act enacted section 387t of this title. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

PRIOR PROVISIONS

A prior section 901 of act June 25, 1938, was renumbered section 1001 and is classified to section 391 of this title.

§ 387a-1. Final rule

(a) Cigarettes and smokeless tobacco

(1) In general

On the first day of publication of the Federal Register that is 180 days or more after June 22, 2009, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which—

(A) is deemed to be issued under chapter 9¹ of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387 et seq.], as added by section 101 of this division; and

(B) shall be deemed to be in compliance with all applicable provisions of chapter 5 of title 5 and all other provisions of law relating to rulemaking procedures.

(2) Contents of rule

Except as provided in this subsection, the final rule published under paragraph (1),² shall

be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615-44618). Such rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection in accordance with this division and the amendments made by this division;

(B) strike Subpart C—Labels and section 897.32(c);

(C) strike paragraphs (a), (b), and (i) of section 897.3 and insert definitions of the terms “cigarette”, “cigarette tobacco”, and “smokeless tobacco” as defined in section 900 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387];

(D) insert “or roll-your-own paper” in section 897.34(a) after “other than cigarettes or smokeless tobacco”;

(E) include such modifications to section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court of the United States in *Lorillard Tobacco Co. v. Reilly* (533 U.S. 525 (2001));

(F) become effective on the date that is 1 year after June 22, 2009; and

(G) amend paragraph (d) of section 897.16 to read as follows:

“(d)(1) Except as provided in subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

“(2)(A) Subparagraph (1) does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

“(B) This subparagraph does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

“(C) For purposes of this paragraph, the term ‘qualified adult-only facility’ means a facility or restricted area that—

“(i) requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

“(ii) does not sell, serve, or distribute alcohol;

“(iii) is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

“(iv) is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this subparagraph;

“(v) is enclosed by a barrier that—

¹ So in original. Probably should be “chapter IX”.

² So in original. The comma probably should not appear.

“(I) is constructed of, or covered with, an opaque material (except for entrances and exits);

“(II) extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

“(III) prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

“(vi) does not display on its exterior—

“(I) any tobacco product advertising;

“(II) a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

“(III) any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate section 897.34(c).

“(D) Distribution of samples of smokeless tobacco under this subparagraph permitted to be taken out of the qualified adult-only facility shall be limited to 1 package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the individual portions of smokeless tobacco shall not exceed 8 individual portions and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the above amounts are limited to one such package per adult consumer per day.

“(3) Notwithstanding subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco—

“(A) to a sports team or entertainment group; or

“(B) at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by this subparagraph.

“(4) The Secretary shall implement a program to ensure compliance with this paragraph and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

“(5) Nothing in this paragraph shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.”.

(3) Amendments to rule

Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with chapter 5 of title 5.

(4) Rule of construction

Except as provided in paragraph (3), nothing in this section shall be construed to limit the

authority of the Secretary to amend, in accordance with chapter 5 of title 5, the regulation promulgated pursuant to this section, including the provisions of such regulation relating to distribution of free samples.

(5) Enforcement of retail sale provisions

The Secretary of Health and Human Services shall ensure that the provisions of this division, the amendments made by this division, and the implementing regulations (including such provisions, amendments, and regulations relating to the retail sale of tobacco products) are enforced with respect to the United States and Indian tribes.

(6) Qualified adult-only facility

A qualified adult-only facility (as such term is defined in section 897.16(d) of the final rule published under paragraph (1)) that is also a retailer and that commits a violation as a retailer shall not be subject to the limitations in section 103(q)³ and shall be subject to penalties applicable to a qualified adult-only facility.

(7) Congressional review provisions

Section 801 of title 5 shall not apply to the final rule published under paragraph (1).

(b) Limitation on advisory opinions

As of June 22, 2009, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document titled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents” (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document titled “Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act” (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document titled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document titled “Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination” (61 Fed. Reg. 44619–45318 (August 28, 1996)).

(Pub. L. 111–31, div. A, title I, § 102, June 22, 2009, 123 Stat. 1830.)

Editorial Notes

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(1)(A), is act June 25, 1938, ch. 675, 52

³ So in original. See References in Text note below.

Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of this title. Chapter 9 [IX] of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This division, referred to in subsec. (a)(2)(A), (5), is div. A of Pub. L. 111-31, June 22, 2009, 123 Stat. 1776, known as the Family Smoking Prevention and Tobacco Control Act. For complete classification of division A to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.

The date of enactment of the Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (a)(2)(G), is the date of enactment of Pub. L. 111-31, which was approved June 22, 2009.

Section 103(q), referred to in subsec. (a)(6), is section 103(q) of Pub. L. 111-31, which enacted provisions set out as notes under sections 333 and 387c of this title.

CODIFICATION

Section was enacted as part of the Family Smoking Prevention and Tobacco Control Act and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

For provision deeming reference to “180 days” in subsec. (a)(1) to be “270 days”, see section 6 of Pub. L. 111-31, set out as a note under section 387 of this title.

§ 387b. Adulterated tobacco products

A tobacco product shall be deemed to be adulterated if—

- (1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;
- (2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;
- (3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- (4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 387s of this title by the date specified in section 387s of this title or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;
- (5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 387g of this title unless such tobacco product is in all respects in conformity with such standard;
- (6)(A) it is required by section 387j(a) of this title to have premarket review and does not have an order in effect under section 387j(c)(1)(A)(i) of this title; or
- (B) it is in violation of an order under section 387j(c)(1)(A) of this title;
- (7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 387f(e)(1) of this title or an applicable condition prescribed by an order under section 387f(e)(2) of this title; or

(8) it is in violation of section 387k of this title.

(June 25, 1938, ch. 675, §902, as added Pub. L. 111-31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1787.)

Editorial Notes

PRIOR PROVISIONS

A prior section 902 of act June 25, 1938, was renumbered section 1002. Subsec. (a) of section 1002 is set out as a note under section 301 of this title. Subsecs. (b) and (c) of section 1002 are classified to section 392 of this title. Subsec. (d) of section 1002 is set out as a note under section 392 of this title.

§ 387c. Misbranded tobacco products

(a) In general

A tobacco product shall be deemed to be misbranded—

- (1) if its labeling is false or misleading in any particular;
- (2) if in package form unless it bears a label containing—
 - (A) the name and place of business of the tobacco product manufacturer, packer, or distributor;
 - (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;
 - (C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and
 - (D) the statement required under section 387t(a) of this title,

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

(3) if any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 387e(b), 387e(c), 387e(d), or 387e(h) of this title, if it was not included in a list required by section 387e(i) of this title, if a notice or other information respecting it was not provided as required by such section or section 387e(j) of this title, or if it does not bear such symbols from